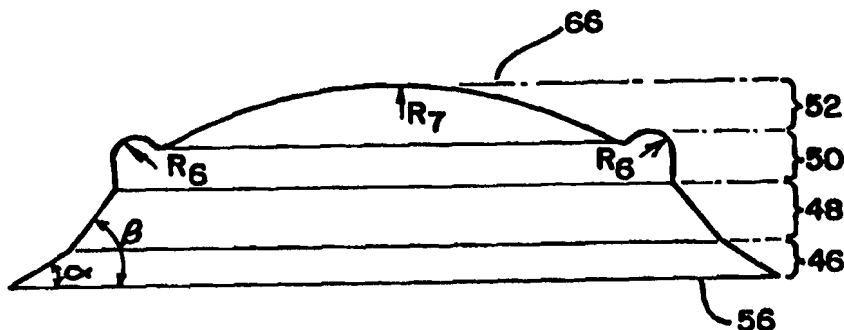


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<b>(21) International Application Number:</b> PCT/US98/09923 <b>(22) International Filing Date:</b> 14 May 1998 (14.05.98) <b>(30) Priority Data:</b> 60/046,747 16 May 1997 (16.05.97) US <b>(71) Applicant (for all designated States except US):</b> CORRECTIVE VISION, INC. [US/US]; National Eye Research Foundation, Suite 207A, 910 Skokie Boulevard, Northbrook, IL 60062 (US). <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> WESLEY, Newton, K. [US/US]; 601 Driftwood Lane, Northbrook, IL 60062 (US). KIM, Andrew, K. [US/US]; Apartment 2, 904-1/2 Green Bay Road, Winnetka, IL 60093 (US). <b>(74) Agents:</b> MORNEAULT, Monique, A. et al.; Wallenstein & Wagner, Ltd., 311 South Wacker Drive - 5300, Chicago, IL 60606 (US).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GW, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

**(54) Title:** IMPROVED CONTACT LENS**(57) Abstract**

A device for creating an imprint on the eye comprising a first zone for facilitating tear exchange, a second zone defining a pressure curve, a third zone defining a relief area for receiving the cornea displaced from the second zone, and a fourth zone defining a base curve for imparting outward pressure on the eye. The first zone is defined by an angle  $\alpha$  relative to the peripheral edge of the device. The second zone appends upwardly from the top edge of the first zone and is defined by an angle  $\beta$ , the angle  $\beta$  being greater than the angle  $\alpha$  defined by the first zone. The third zone appends from the top edge of the second zone and is defined by a concave surface having a radius of curvature  $R_6$ . The fourth zone appends from the top edge of the third zone and forms a generally concave dome having a predetermined radius of curvature  $R_7$ .

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## IMPROVED CONTACT LENS

### DESCRIPTION

#### Technical Field

The present invention relates generally to both hard and soft contact lenses and the method of manufacturing the same. More particularly, the present invention relates to significantly decreasing the amount corneal coverage with the improved contact lens and the manufacture of such a lens. The invention further relates to facilitating the positioning of the contact lens on the eye, and the shaping thereof.

5

**Background Of The Invention**

There are many problems associated with contact lenses. Although there have been great improvements in contact lens technology, and there are many choices in brand, material, and color available, standard hard and soft contact lenses still require significant care that further requires many different cleaning, disinfecting, and lubricating solutions some of which can be expensive. In addition, many of these standard lenses create problems with vision and dry eyes. Due to these problems, patients cannot wear their contact lenses without thinking of them.

The movement in the contact lens industry has been toward making lenses larger to cover, at least, the full cornea of the eye. Corneal contact lenses typically have a diameter of approximately 11.5 to 12 mm. This larger size affects the ability to wear the contact lenses for extended periods of time. To extend the time over which these lenses may be worn, some inventors have attempted to duplicate human tears. These artificial tears must be placed in the user's eye and involve considerable cost and inconvenience to the wearer. These artificial solutions also contain preservatives which are foreign to the eye. Moreover, these solutions have been known to cause allergic reactions in some wearers that result in gross discomfort.

Another problem associated with the larger contact lenses is gaining a proper fit to the patient's eye. Irregularities in the shape of the patient's eye and his/her palpebral fissure must be accounted for in the fitting process. In addition, the larger sized contact lenses do not correct astigmatism effectively.

The larger contact lenses also restrict the oxygen exchange between the eye and the environment. Heat builds under these lenses and removal of carbon dioxide is difficult as is removal of by-products of metabolism, including lactic acid.

Many modern contact lenses are not balanced or properly matched to the eye. This results in another problem for contact lens patients as they suffer with excessive lens movement over the eye. This causes discomfort and often results in a lost lens.

Wearers of contact lenses experience difficulty centering the contact lenses on their eyes. It is, therefore, difficult for these wearers to place the contact lens in a location where maximum vision correction is achieved. Lack of centering

also causes the wearer to experience ghost images when the contact lenses are removed. The contact lens patient often adjusts the lens by moving his/her head. This head motion causes light dispersion and flare resulting in impaired vision.

Also, wearers of soft contact lenses experience a ripple effect of the upper lid on each blink over the contact lens. This is often referred to as a "cellophane fit" and adversely affects the tear exchange between the wearer's eye and the contact lens. This effect negatively impacts the patient's vision as well.

To date, no one has suggested reducing the size of the contact lens to overcome these disadvantages. Recent disclosures of reduced-sized contact lenses have been associated with the correction of vision in patients suffering from presbyopia. These disclosures pertain to placing a smaller bifocal lens on the posterior or anterior side of a larger contact lens. Examples of these disclosures are U.S. Patent No. 4,728,182 issued to Kelman, U.S. Patent No. 5,141,301 issued to Morstad, U.S. Patent No. 5,434, 630 issued to Bransome, and U.S. Patent No. 5,608,471 issued to Miller.

There has also been a movement in the contact lens industry toward correcting vision using orthokeratology treatment. Generally, orthokeratology is a corrective eye care procedure in which the corneal contour is reshaped to achieve at least functional vision in an eye patient. The procedure can be employed to reduce myopia as well as to alter the focus of the eye. Typically, the orthokeratology patient wears a contact lens that acts as a retainer and which maintains a desired corneal shape. If the desired result is to correct myopia, the contour of the cornea is flattened. Alternatively, if the patient is seeking to correct astigmatism, the cornea is made more spherical.

There have been recent disclosures directed toward devices that may be used for orthokeratology treatment. For example, U.S. Patent No. 5,695,509 to El Hage discloses an optical mode for reshaping the surface of the cornea. The mold has an inner concave surface matched to the topography of the cornea. The mold disclosed in the '509 patent includes a pressure zone, a relief zone, and an anchor zone to control and direct movement of displaced corneal tissue. The pressure zone applies pressure to the cornea and displaces the underlying corneal tissue. The curvature of the mold may be modified to match the patient's corneal topography.

While molds such as the device disclosed in the '509 patent have enjoyed some degree of success, the molds do not address the problems associated with properly positioning a contact lens on the eye.

5 As discussed above, many modern contact lenses, including those prescribed for orthokeratology, are not balanced or do not properly match the eye. Such an imbalance may result in improper positioning of the contact lens on the eye. Inaccuracy in positioning of the contact lens may, in turn, result in failure to displace the cornea as desired during the orthokeratological treatment.

10 Another disadvantage of current orthokeratology treatment is the increased stress on the eye because of overnight wear. Increased stress on the eye can occur because of the reduced breathing capacity and lack of oxygen flow to the eye during overnight use.

There is a need for a contact lens and contact lens fitting device that overcomes these and other disadvantages.

15

### **Summary of the Invention**

The present invention provides a reduced-sized contact lens which overcomes the disadvantages of the prior art. More particularly, the present invention pertains to a reduced-sized contact lens having a diameter between 2 and 5 mm. The posterior side of this reduced-sized contact lens is positioned on the pupil portion of the patient's eye.

20 One object of the present invention is to provide a contact lens that restores the eye's normal physiological effects.

25 Another object of the present invention is to provide a contact lens that is fit to the periphery of the optic cap.

Another object of this invention is to reduce the amount of coverage of the cornea to only the central area in front of the pupil.

Another object of the present invention is to reduce the diameter of the contact lens to between approximately 2 to 5 mm.

30 Another object of the present invention is to provide a contact lens with improved edge factors.

Another object of the present invention is to provide a contact lens that

minimizes upper eye lid resistance.

Another object of the present invention is to minimize the effects of interference of outside optical rays.

5 Another object of the present invention is to provide a contact lens that requires less tear pump.

Another object of the present invention is to provide a significantly thinner contact lens.

Another object of the present invention is to provide that will follow the contour of the tears with minimal impediment to the upper eye lid.

10 Another object of the present invention is to provide a contact lens that minimizes the need for artificial wetting agents.

Another object of the present invention is to provide a contact lens that improves vision correction.

15 Another object of the present invention is to provide a contact lens with improved centering.

Another object of the present invention is to provide an extended wear contact lens.

Another object of the present invention is to provide a device for creating an imprint on the eye.

20 Another object of the present invention is to provide a contact lens that can be used for orthokeratology.

Other features and advantages of the invention will be apparent from the following specification taken in conjunction with the following drawings.

25 **Brief Description Of The Drawings**

Figure 1 is a partial cross-sectional view of a human eye with the contact lens of the present invention placed over the optic cap;

Figure 2 is a front perspective view of the contact lens according to the present invention;

30 Figure 3 is a cross-sectional view of one embodiment of the contact lens according to the present invention;

Figure 4 is a cross-sectional view of one embodiment of the contact

lens according to the present invention;

Figure 5 is a cross-sectional view of a contact lens as used as an imprint device in accordance with the present invention;

Figure 6 is a top view of the double optical zone configuration according to the present invention.

Figure 7 is a cross-sectional view of the double optical zone configuration according to the present invention, taken along the line 7-7 of Figure 6.

#### 10 **Detailed Description Of The Preferred Embodiment**

While this invention is susceptible of embodiments in many different forms, there is shown in the drawings and will herein be described in detail a preferred embodiment of the invention with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the broad aspect of the invention to the embodiment illustrated.

Figure 1 is a partial cross-sectional view of a human eye fitted with a contact lens 10 of the present invention. This contact lens 10 fits over the ocular or tear side of the optic cap of the eye covering a distance approximately equal to the pupil. Figure 2 shows this contact lens 10 in front perspective view. The contact lens 10 is characterized by a longitudinal axis 12 which runs perpendicular to a latitudinal axis 14. These axes intersect at approximately the center 15 of the contact lens 10.

Still referring to Figure 2, the longitudinal axis defines a first vertical distance 16. The first vertical distance 16 corresponds to the longitudinal length of the pupil. In the preferred embodiment, the latitudinal axis defines a first horizontal distance 18 corresponding to the latitudinal length of the pupil. The target diameter of the contact lens 10 is 2 to 5 mm which is much smaller than typical contact lenses that generally have diameters of 11.5 to 15 mm. Although the preferred embodiment discloses an optic cap that is hemispherical, the optical cap may also assume an aspherical or elliptical configuration. Therefore, the axes may create oblique angles rather than angles equaling 360°.

One purpose of the target diameter is to reduce the amount of coverage



of the cornea to only the central portion in front of the pupil. Since the spherical center is being corrected there would be better visual acuity. Reduction of the diameter allows the uncovered portion of the cornea to breathe. This improves the patient's comfort because the cornea experiences a more normal exchange of oxygen and removal of carbon dioxide and lactic acid as well as other by-products of metabolism.

Reducing the diameter of the lens also has the aesthetically pleasing effect of reducing redness in the sclera. This redness occurs in conjunction with the wearing of standard contact lenses because the eye is deprived of oxygen. As the eye is deprived of oxygen, the blood vessels in the sclera grow to compensate for the lack of oxygen entering the cornea. With the improved oxygen exchange provided by the contact lens 10, comes a corresponding decrease in redness.

The smaller target diameter also means that the contact lens 10 must account for fewer irregularities in the shape of the cornea's surface. The patient's palpebral fissure would not have to be taken into consideration because neither the upper eye lid nor the lower eye lid would intersect the outer circumference of the contact lens 10 when the eye lids are opened. Many patients have lower eye lids that extend very high up the eye, the contact lens 10 of the present invention would minimize the effect that the position of the lower eye lid has on fit and comfort.

Referring to Figure 3, the contact lens of the present invention further comprises an outer peripheral portion 20. The outer peripheral portion 20 forms the portion of the contact lens 10 which surrounds the inner central portion 22 of the contact lens 10. The inner central portion 22 is curved so that a radius  $R_0$  approximates the surface curvature of the optic cap. This inner central portion 22 may be curved to other specifications such as toric surfaces as well as of any one of a number of the conic sections including, but not limited to, parabolic or ellipsoid. Furthermore, bifocal, trifocal, and progressive contact lenses can be made using the concepts of the present invention.

The inner central portion 22 is further characterized by a thickness  $T_0$ . This thickness  $T_0$  is significantly thinner than previous contact lens' design. The thinner thickness  $T_0$  improves the cohesive and adhesive forces that keep the contact lens 10 positioned properly on the eye. A thinner lens also means that the contact

lens 10 will be lighter in weight than most conventional contact lenses. Therefore, this contact lens 10 will be more comfortable for the wearer.

5 A typical thickness  $T_0$  for a -2.50 contact lens of the present invention having a diameter of 3 mm would be approximately .004 inches at the center 15. An A+ contact lens of the present invention would be approximately .008 inches at the center 15. However, the thickness  $T_0$  can vary depending on sizing and shaping of the material used.

10 The outer peripheral portion 20 serves a number of functions. This outer peripheral portion 20 is the region of the contact lens that provides a blending tear layer to remove normal flare and dispersion of light. Applying different edge factors to the outer peripheral portion 20 will prevent dust, lint, and other debris from getting under the lens.

15 The pupil is usually 2 to 3 mm in diameter and changes with convergence, constricting as an object nears the eye and dilating as the object moves away from the eye. The pupil also changes size in reaction to changes in light. If the amount of light increases, the pupil constricts; if the amount of light lessens, the pupil dilates. The pupil will often dilate to the margin of the iris. The prevailing view is that the pupil size affects light dispersion at the edge of the contact lens. By creating the proper edge factors that follow the contour of the tears and blending the edge with the tears, this effect can be minimized or reduced entirely. In addition, coloring can change the light dispersion.

20 One edge factor is the beveled edge 24 shown in Figure 3. The beveled edge 24 uses a ski-like shape to control fit and positioning and improve tear flow while maintaining minimum interference with the eye lids. Tear flow is aided by a reservoir 25 which is formed between the beveled edge 24 and the eye. Microscopic factors such as push, angle factor, resistance, and tear wave characteristics are improved by the beveled edge 24. The beveled edge 24 promotes a glide feeling as the upper eye lid blinks over the transition zone between the reservoir 25 and beveled edge 24. Thus, the eye lid action which affects fit, positioning, sharpness of vision, etc. would be minimal.

30 The beveled edge 24 is located at the peripheral portion 20. The beveled edge 24 is formed as an anterior side 26 of the contact lens 10 transitions into

a convex outer edge 32 having a radius of curvature  $R_1$ . The radius of curvature  $R_1$  of the convex outer edge 32 may be adjusted to improve lens push, lift, and glide. Even minimal modifications in  $R_1$  can have a significant effect in a contact lens 10 of this small size. The convex outer edge 32 is the portion of the contact lens 10 which is at the furthest radial distance from the center 15 of the anterior side 26.

The structure of the beveled edge 24 is completed by a concave inner wall 34 having a radius of curvature  $R_2$ . The concave inner wall 34 extends from the convex outer edge 32 toward the center 15 of the contact lens 10 and away from the cornea. This concave inner wall 34 forms the contact lens 10 side of the tear reservoir 25 which enables the eye lid to glide over the outer peripheral portion 20.

Another edge factor further enables the contact lens 10 to remain in proper position. A convex wing portion 36 can be utilized to achieve an effect similar to the leading edge of a wing on an airplane. This effect creates a vacuum whereby the contact lens 10 remains in position on the cornea. The concave wing portion 36 has a radius of curvature  $R_3$ . The concave wing 36 is joined to the posterior side 38 of the inner central portion 22 by a concave wing positioning portion 40. The concave wing positioning portion is characterized by a radius of curvature  $R_4$ .

In an alternative embodiment shown in Figure 4, the contact lens 10 of the present invention exhibits a convex rolled edge 42. The convex rolled edge 42 has a radius of curvature  $R_5$ . Similar to the previously disclosed embodiment, the radius of curvature  $R_5$  can be regulated to improve fit characteristics.

These edge factors along with the reduced size of the contact lens 10 of the present invention allows the patient to wear his/her contact lenses comfortably for extended periods of time. The need for expensive artificial solutions and their associated preservatives will be eliminated because this reduced-size contact lens provides improved osmosis over a smaller area, and the contact lens' tear flow characteristics provide a more efficient use of naturally produced tears.

The patient enjoys many residual benefits due to increased wear time. Handling of the contact lens is decreased, so there is a decrease in the risk of infection to the eye. The useful life of the contact lens is extended because less scratching of the contact lens will occur. Moreover, the patient is less likely to lose these contact

lenses because the lenses are always in his/her eyes.

5 The contact lens 10 of the present invention further comprises channels 44 in the outer peripheral portion 20 (See Figure 2). These channels 44 are characterized by microscopic slits. Figure 2 shows these channels 44 cut circularly about the inner central portion 22. However, the channels 44 may be cut in radial dispersion throughout the outer peripheral portion 20. Alternatively, a combination of the different types of channels 44, circular and radial, may be cut into the contact lens.

10 The channels 44 act in combination with the contact lens' other characteristics, such as weight, size and shape, including various types of conic section curves, toroidal base curves, toroidal intermediate curves, para and peripheral curves, to control fit, hasten movement, and improve control and tear flow. The depths of the channels 44 may be varied to further enhance these benefits. These lens' characteristics have a particularly beneficial effect on centering the contact lens 10 on the eye.

15 This contact lens 10 can be manufactured from a number of different materials. For instance, the contact lens 10 can be produced from a semi-hard or hard polymer similar to conventional hard contact lenses. It can be produced from a gas permeable polymer like a rigid gas permeable (RGP) lens. Alternatively, it can take on the characteristics of a standard soft contact lens by producing it from a soft silicone polymer or soft hydrogel polymer. The scope of the invention is not limited to the present materials but can be applied to any material in which optical properties are present and which is capable of being molded or machined, ground and polished. and/or with the use of a laser. Any material development in which the concepts of this invention are applied would come under the scope of this patent.

20 The contact lens 10 of the present invention can be placed on the eye in a number of ways. In the beginning, the doctor would place the lens on the eye and center it over the visual axis. The patient will be taught to place the contact lens 10 on his/her eye and position it.

30 Alternatively, an eye care professional could fix the contact lens 10 in the patient's eye by surgically suturing or gluing the contact lens 10 in place by any practical means.

In an alternative embodiment of the present invention, depicted in Figures 5-7, an imprint device 66, such as a contact lens, for creating an imprint on the eye is provided. Generally, such an imprint device 66 has a convexo-concave contact surface. Although the embodiment in Figures 5-7 provides that the imprint device 66 is the contact lens 10 which has a diameter of between 2 and 5 mm, it is contemplated that the imprint device 66 can be a conventional contact lens with a diameter of between 11.5 to 15 mm. However, as discussed above, employing the contact lens 10 with the smaller diameter improves the patient's comfort because the cornea experiences a more normal exchange of oxygen and removal of carbon dioxide and lactic acid as well as removal of other by-products of metabolism. It is further contemplated that the imprint device 66 can be a hand held or other device commensurate with the configuration set forth below.

Referring to Figure 5, the contact surface of the imprint device 66 is characterized by four zones: the peripheral curve 46, the pressure curve 48, the relief area 50, and the base curve 52. The first zone, the peripheral curve 46, facilitates tear exchange. The peripheral curve 46 has a top edge and a bottom edge, wherein the bottom edge defines a peripheral edge 56 of the imprint device 66. The peripheral edge 56 fits over the ocular or tear side of the optic cap of the eye. The peripheral curve 46 is defined by an angle  $\alpha$  relative to the peripheral edge 56 of the imprint device 66.

The second zone, or the pressure curve 48, applies a predetermined pressure to the cornea. The pressure curve 48 has a top edge and a bottom edge and appends upwardly from the top edge of the peripheral curve 46. The peripheral curve 48 is defined by an angle,  $\beta$  relative to the peripheral edge 56 of the imprint device 66. The angle,  $\beta$ , is greater than the angle,  $\alpha$ , defined by the peripheral curve 46.

The third zone of the imprint device 66 defines a relief area 50. The relief area 50 receives the cornea displaced from the pressure curve. Generally, the relief area 50 has a top edge and a bottom edge and appends from the top edge of the second zone. The third zone is characterized by a generally concave surface having a radius of curvature  $R_6$ . The radius of curvature  $R_6$  creates a pocket into which the cornea from the relief area 50 is displaced.

The fourth zone of the imprint device 66 defines the base curve 52 of

the device. The base curve 52 imparts outward pressure on the eye when the surface is contacting the eye. The base curve 52 has a top edge and a bottom edge and appends from the top edge of the relief area 50. The base curve 52 forms a generally concave dome 58 having a predetermined radius of curvature  $R_7$ . It is contemplated that the base curve 52 may be spherical or aspherical, or a combination of both.

As discussed above, the pressure created by the pressure curve 46 displaces a portion of the cornea to the relief area 50. The portion of the cornea displaced into the relief area 50 is collected within the zone 50, thereby resulting in corneal molding. The pressure curve 48 also assists in centering a contact lens 10 on the eye. The base curve 52 is fit steeper or flatter, depending on the patient's eye, i.e., depending on the steepness of the optical cap. It is further contemplated that the base curve 52 may be either negative or positive. A positive aspheric base curve 52 will act to smoothen the cornea to create an orthokeratology effect. Alternatively, a negative base curve 52 may be used for corneal molding and creating a presbyopic molding effect.

As shown in Figures 6 and 7, a second contact lens 60 may be disposed above a first contact lens 10 to create a double optical zone 62. Such a double optical zone 62 may be used to address issues such as contact lens weight, positioning or lid obstruction. When employing this configuration, the second contact lens 60 can be fused to the first contact lens 10 thereby creating a space 64 between the first contact lens 10 and the second contact lens 60. In the preferred embodiment, the second contact lens 60 is fused to the first contact lens at the peripheral edge of the second contact lens. However, the contact lenses 10, 60 may be fused anywhere along the surface of the lens. The point at which to fuse the lenses 10, 60 will vary with the needs of the patient, i.e., depending on whether the patient is myopic or astigmatic.

The space 64 may be filled by a fluid, including hydrogel polymer or a liquid. However, the scope of the invention is not limited to the present materials but to any fluid suitable for filling the space 64. The space 64 between the two lenses 10, 60 may be altered to enhance the vision by altering the relationships of the curve between the two lenses 10, 60. It is contemplated that the double optical zone 62 may be used with two of conventional 11.5 to 15 mm contact lenses, or a pair of the

smaller 2 to 5 mm contact lenses described above. It is further contemplated that a conventional 11.5 to 15 mm contact lens be used in combination with the smaller 2 to 5 mm contact lens. Such a combination can be used to reshape the cornea of a myopic, astigmatic or hyperopic patient.

5                   Another aspect of the present invention discloses that peripheral rings may be disposed along the periphery of the contact lens 10 to enhance a patient's vision and alter a patient's perception of light or color. The peripheral rings create tunnelvisioning by decreasing the size of the lens through which a patient must look.

10                   The eye then effectively blocks out the peripheral rings and interprets only the exposed center of the contact lens 10, thereby improving the patient's vision. It is further contemplated that rings of varying size be disposed in series at varying spacing intervals on the contact lens. The peripheral rings may be used with a conventional 11.5 to 15 mm. contact lens, or the smaller 2 to 5 mm contact lens described above.

15                   While the specific embodiment has been illustrated and described, numerous modifications come to mind without significantly departing from the spirit of the invention, and the scope of protection is only limited by the scope of the accompanying Claims.

CLAIMS

What is claimed is:

- 5 1. An apparatus to be placed on an eye for correcting vision impairments comprising:  
a contact lens, the contact lens having a longitudinal axis and a latitudinal axis, the longitudinal axis being perpendicular to the latitudinal axis, and the contact having a first dimension, the first dimension being parallel to the longitudinal axis and having a length of between 2.0 and 5.0 mm.
- 10 2. The contact lens of Claim 1 further comprising a second contact lens disposed above the first contact lens, wherein the second lens is fused to the first contact lens and a space is created between the first contact lens and the second contact lens.
- 15 3. The contact lens of Claim 2, wherein the space between the first contact lens and the second contact lens is filled with a hydrogel polymer.
4. The contact lens of Claim 2, wherein the space between the first contact lens and the second contact lens is filled with a liquid.
- 20 5. The contact lens of Claim 1, further including rings on the peripheral edge of the contact lens.
6. The contact lens of Claim 1, further including a plurality of rings spaced at  
25 varying distances from the peripheral edge of the contact lens.
7. The apparatus of claim 1 wherein the contact lens is placed over at least a portion of an optic cap of the eye.
- 30 8. The apparatus of claim 2 wherein the first dimension is equal to a corresponding longitudinal length of the at least a portion of the optic cap of the eye.



9. The apparatus of claim 1 wherein the contact lens further includes a second dimension, the second dimension being parallel to the latitudinal axis and being equal in length to the first dimension.
- 5 10. The apparatus of claim 1 wherein the contact lens is centered over the optic cap.
11. The apparatus of claim 1 wherein the contact lens further comprises an outer peripheral edge, the outer peripheral edge being circumferentially positioned about  
10 a center portion of the contact lens.
12. The apparatus of claim 6 wherein the outer peripheral edge comprises at least one circumferential channel for controlling fit and movement of the contact lens against the eye.
- 15 13. The apparatus of claim 6 wherein the outer peripheral portion comprises at least one radial channel, the at least one radial channel for controlling fit and movement of the contact lens against the eye.
- 20 14. The apparatus of claim 6 wherein the outer peripheral edge comprises at least one circumferential channel and at least one radial channel for controlling fit and movement of the contact lens against the eye.
- 25 15. The apparatus of claim 6 wherein a shape of the outer peripheral edge corresponds to an outer circumferential portion of the optic cap.
16. The apparatus of claim 6 wherein the outer peripheral edge includes a means for providing an uninterrupted tear flow around the contact lens.
- 30 17. The apparatus of claim 11 wherein the means for providing an uninterrupted tear flow comprises a beveled inside curve, the beveled inside curve oriented such that a reservoir is formed between the eye and the outer peripheral edge.

18. The apparatus of claim 12 wherein the reservoir captures tears produced by the eye to form an uninterrupted tear layer over the outer peripheral edge of the contact lens.

5 19. The apparatus of claim 11 wherein the means for providing an uninterrupted tear flow comprises a rolled edge, the rolled edge providing smooth transition between the outer peripheral edge of the contact lens and the eye, the rolled edge further providing the least amount of obstruction to the lid shape of the margins of the lid.

10

20. The apparatus of claim 1 wherein the contact lens further comprises a posterior portion and an opposing anterior portion, the posterior portion being positioned adjacent the optic cap of the eye.

15 21. The apparatus of claim 15 wherein the posterior portion of the contact lens has a toric shape.

22. The apparatus of claim 15 wherein the posterior portion of the contact lens is molded to a shape of the optic cap.

20

23. The apparatus of claim 15 wherein the posterior portion of the contact lens follows a generally spherical curve.

24. The apparatus of claim 15 wherein the posterior portion of the contact lens  
25 follows a generally elliptical curve.

25. The apparatus of claim 15 wherein the posterior portion of the contact lens follows a generally parabolic curve.

30 26. The apparatus of claim 1 wherein the contact lens is produced from an oxygen permeable, semi-hard or hard polymer.

27. The apparatus of claim 1 wherein the contact lens is produced from a soft hydrogel polymer.

28. The apparatus of claim 1 wherein the contact lens is produced from a soft  
5 silicone polymer.

29. The apparatus of claim 1 wherein the contact lens further includes a bifocal region.

10 30. The apparatus of claim 1 wherein the contact lens further includes a trifocal region.

31. A method for surgically attaching a contact lens to the eye wherein, the contact lens has a longitudinal axis and a latitudinal axis, the longitudinal axis being  
15 perpendicular to the latitudinal axis, and the contact further has a first dimension, the first dimension being parallel to the longitudinal axis and having a length of between 2.0 and 5.0 mm.

32. A device for creating an imprint on the eye, the device generally having a  
20 convexo-concave surface, the surface comprising:

a first zone for facilitating tear exchange having a top edge and a bottom edge and a bottom edge, the bottom edge defining a peripheral edge of the contact lens, the first zone being defined by an angle  $\alpha$  relative to the peripheral edge;

a second zone having a top edge and a bottom edge, the second zone defining  
25 a pressure curve, the second zone appending upwardly from the top edge of the first zone, the second zone being defined by an angle  $\beta$  the angle  $\beta$  being greater than the angle  $\alpha$  defined by the first zone;

a third zone having a top edge and a bottom edge, the third zone defining a  
30 relief area for receiving the cornea displaced from the second zone, the third zone appending from the top edge of the second zone and being defined by a concave surface having a radius of curvature  $R_6$ ; and,

a fourth zone having a top edge and a bottom edge, the fourth zone appending from the top edge of the third zone and defining a base curve, the fourth zone forming a generally concave dome having a predetermined radius of curvature  $R_7$ , the base curve imparting outward pressure on the eye when the surface is contacting the eye.

5

33. The device of Claim 32, wherein the device for creating an imprint on the eye is a first contact lens.

10

34. The contact lens of Claim 33 further comprising a second contact lens disposed above the first contact lens, wherein the second lens is fused to the first contact lens and a space is created between the first contact lens and the second contact lens.

15

35. The contact lens of Claim 34, wherein the space between the first contact lens and the second contact lens is filled with a hydrogel polymer.

36. The contact lens of Claim 34, wherein the space between the first contact lens and the second contact lens is filled with a liquid.

20

37. The contact lens of Claim 33, further including rings on the peripheral edge of the contact lens.

38. The contact lens of Claim 33, further including a plurality of rings spaced at varying distances from the peripheral edge of the contact lens.

25

39. The contact lens of claim 33, wherein the contact lens includes a longitudinal axis and a latitudinal axis, the longitudinal axis being perpendicular to the latitudinal axis, and the contact lens having a first dimension parallel to the longitudinal axis, wherein the first dimension has a length of between 2.0 and 5.0 mm.

30

40. The contact lens of claim 39 wherein the contact lens is placed over at least a portion of an optic cap of the eye.

41. The contact lens of claim 40 wherein the first dimension is substantially equal to a corresponding longitudinal length of the at least a portion of the optic cap of the eye.

5

42. The contact lens of claim 39 wherein the contact lens further includes a second dimension, the second dimension being parallel to the latitudinal axis and being substantially equal in length to the first dimension.

10

43. The contact lens of claim 39 wherein the contact lens is centered over the optic cap.

44. The contact lens of claim 39 wherein the contact lens further comprises an outer peripheral edge being circumferentially positioned about a center portion of the contact lens.

15

45. The contact lens of claim 44 wherein the outer peripheral edge comprises at least one circumferential channel for controlling fit and movement of the contact lens against the eye.

20

46. The contact lens of claim 44 wherein the outer peripheral portion comprises at least one radial channel for controlling fit and movement of the contact lens against the eye.

25

47. The contact lens of claim 44 wherein the outer peripheral edge comprises at least one circumferential channel and at least one radial channel for controlling fit and movement of the contact lens against the eye.

30

48. The contact lens of claim 44 wherein a shape of the outer peripheral edge corresponds to an outer circumferential portion of the optic cap.

49. The contact lens of claim 44 wherein the outer peripheral edge includes means for providing an uninterrupted tear flow around the contact lens.

5 50. The contact lens of claim 49 wherein the means for providing an uninterrupted tear flow comprises a beveled inside curve forming a reservoir between the eye and the outer peripheral edge.

10 51. The contact lens of claim 50 wherein the reservoir captures tears produced by the eye to form an uninterrupted tear layer over the outer peripheral edge of the contact lens.

15 52. The contact lens of claim 39 wherein the means for providing an uninterrupted tear flow comprises a rolled edge, the rolled edge providing smooth transition between the outer peripheral edge of the contact lens and the eye, the rolled edge further providing the least amount of obstruction to the lid shape of the margins of the lid.

20 53. The contact lens of claim 39 wherein the contact lens further comprises a posterior portion and an opposing anterior portion, the posterior portion being positioned adjacent the optic cap of the eye.

54. The contact lens of claim 53 wherein the posterior portion of the contact lens has a toric shape.

25 55. The contact lens of claim 53 wherein the posterior portion of the contact lens is molded to a shape of the optic cap.

56. The contact lens of claim 53 wherein the posterior portion of the contact lens follows a generally spherical curve.

30 57. The contact lens of claim 53 wherein the posterior portion of the contact lens follows a generally elliptical curve.

58. The contact lens of claim 53 wherein the posterior portion of the contact lens follows a generally parabolic curve.

5 59. The contact lens of claim 39 wherein the contact lens is produced from an oxygen permeable, semi-hard or hard polymer.

60. The contact lens of claim 39 wherein the contact lens is produced from a soft hydrogel polymer.

10

61. The contact lens of claim 39 wherein the contact lens is produced from a soft silicone polymer.

15 62. The contact lens of claim 39 wherein the contact lens further includes a bifocal region.

63. The contact lens of claim 39 wherein the contact lens further includes a trifocal region.

20 64. The contact lens of Claim 39 further comprising a second contact lens disposed above the first contact lens, wherein the second lens is fused to the first contact lens and a space is created between the first contact lens and the second contact lens.

25 65. The contact lens of Claim 64 wherein the space between the first contact lens and the second contact lens is filled with a hydrogel polymer.

66. The contact lens of Claim 64 wherein the space between the first contact lens and the second contact lens is filled with a liquid.

30

67. The contact lens of Claim 39 further comprising rings on the peripheral edge of the contact lens.

68. The contact lens of Claim 39 further comprising a plurality of rings spaced at varying distances from the peripheral edge of the contact lens.



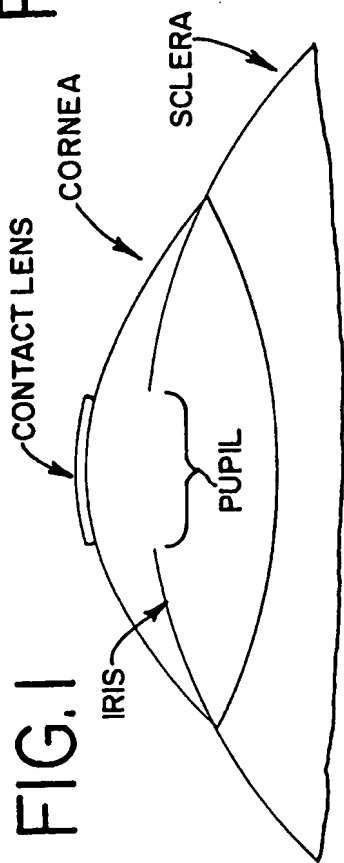


FIG. 2

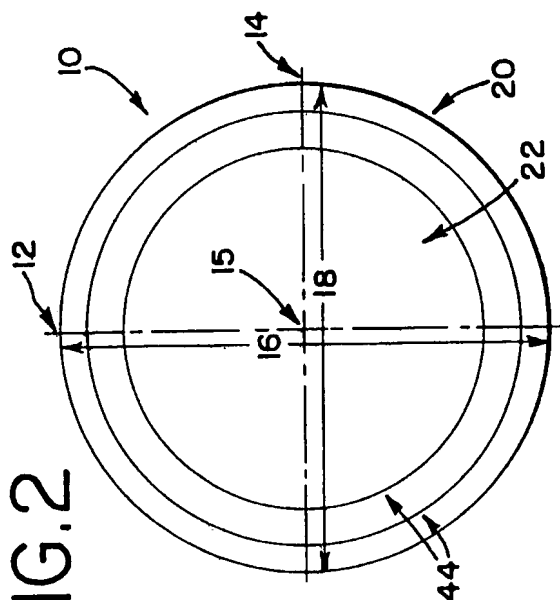


FIG. 3

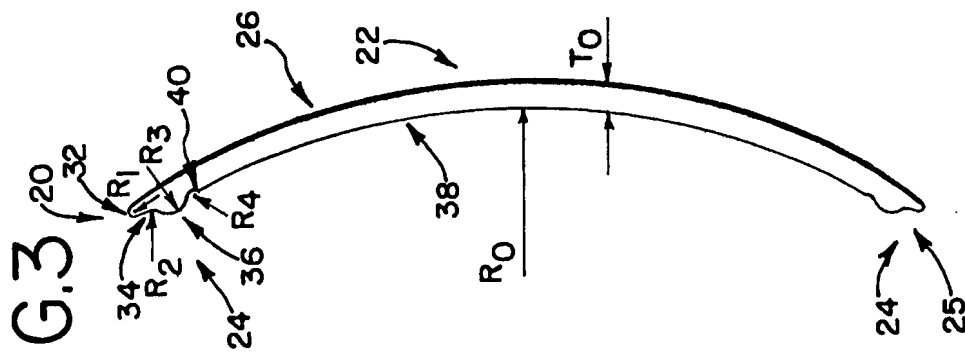


FIG. 4

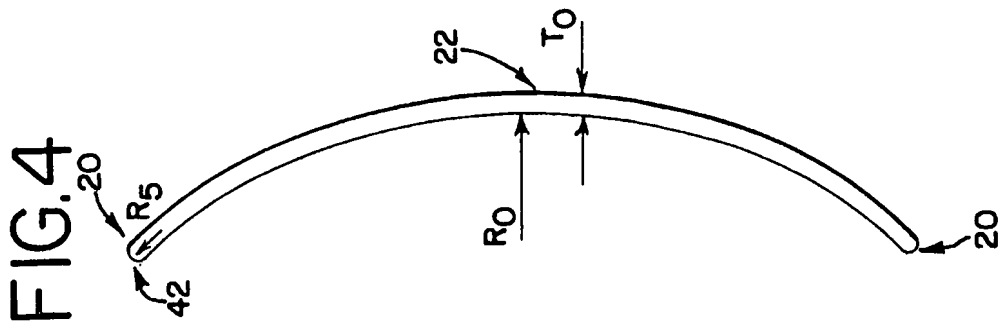


FIG.5

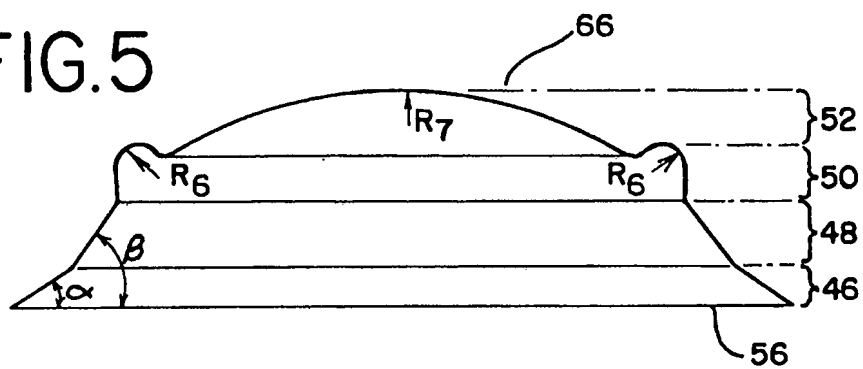


FIG.6

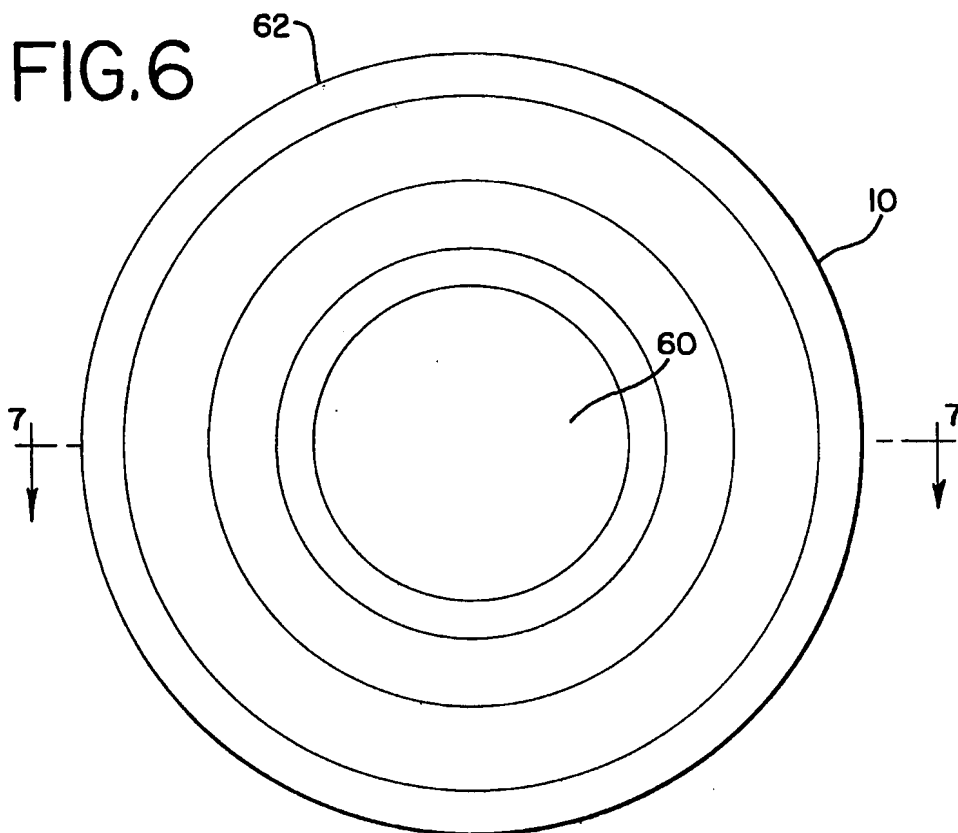
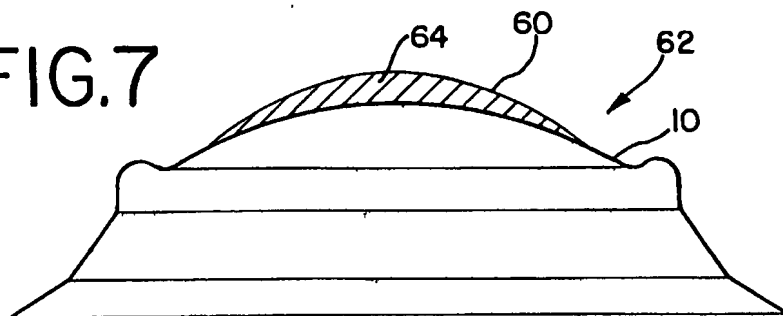


FIG.7



# INTERNATIONAL SEARCH REPORT

ational Application No

PCT/US 98/09923

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 G02C7/04

According to International Patent Classification(IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 G02C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 594 074 A (ROSEN HYMAN) 20 July 1971  see the whole document ---	1,7, 12-18, 27,32, 33,39, 44-51,60
A	CA 1 028 882 A (NEWMAN WILLIAM) 4 April 1978 see claims; figures ---	1,2,7, 32,34
A	US 3 472 581 A (BRONSTEIN LEONARD) 14 October 1969 see abstract see column 3, line 74 - column 5, line 6 --- -/--	1,2,23, 29,30



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

25 August 1998

Date of mailing of the international search report

09/09/1998

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# INTERNATIONAL SEARCH REPORT

National Application No  
PCT/US 98/09923

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